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Dated: April 21, 2003

Signature: *Sharon M. Smith*
(Sharon M. Smith)

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Docket No.: 01017/37128C
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Eugene Medlock, et al

Application No.: 10/037,591

Group Art Unit: 1646

Filed: December 21, 2001

Examiner: J. Dong

For: IL-17 LIKE MOLECULES AND USES
THEREOF

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RESPONSE TO RESTRICTION REQUIREMENT WITH TRAVERSE

Commissioner for Patents
Washington, DC 20231

Dear Sir:

In response to the restriction requirement dated March 21, 2003, the Patent Office alleged pending claims 1-78 were directed to fifteen distinct inventions and require restriction. This response is timely filed.

I. Restriction

Citing 35 U.S.C. § 121, the Examiner alleged that claims 1-77 were drawn to 15 distinct inventions:

I. Claims 1-8, 10 and 11, drawn to an isolated nucleic acid, a vector containing the same, a host cell thereof, a method of recombinantly producing the encoded polypeptide, and a fusion protein;

II. Claims 9, 13-26, and 60, 61 and 68, drawn to an isolated polypeptide and a fusion protein thereof;

III. Claim 12, drawn to a process for determining the polypeptide inhibiting activity of a compound;

IV. Claims 27-30, 32-47, 49, and 50, drawn to an antibody or fragment thereof, and a hybridoma thereof;

V. Claim 31, drawn to a method of detecting or quantifying the polypeptide with the antibody;

VI. Claims 48 and 69-73, drawn to a method of treating, preventing, or ameliorating an IL-17 like polypeptide related disease, condition, or disorder with an antibody;

VII. Claims 51-56 and 62, drawn to a composition of the polypeptide and a method of treatment using the polypeptide;

VIII. Claims 57-59, drawn to a composition of the nucleic acid;

IX. Claim 63, drawn to a method of diagnosis by determining the presence or amount of the polypeptide;

X. Claim 64, drawn to a device;

XI. Claim 65, drawn to a method of identifying a compound binding to the polypeptide;

XII. Claim 66, drawn to a method of modulating levels of the polypeptide in an animal by administering the nucleic acid;

XIII. Claim 67, drawn to a transgenic non-human mammal comprising the nucleic acid;

XIV. Claim 74-76, drawn to a method of antagonizing the activity of an IL-17 like polypeptide, or treating a condition with an IL-17 like polypeptide antagonist; and

XV. Claim 77, drawn to a method of treating a condition with an IL-17 like polypeptide antagonist.

The Examiner further restricted the above-identified groups into three additional groups comprising specific sequences: SEQ ID NOS: 1 and 2, SEQ ID NO: 3 and 4, and SEQ ID NOS: 9 and 10.

II. Election

The applicants hereby elect Group I, which includes claims 1-8, 10, and 11, drawn to an isolated nucleic acid of SEQ ID NO: 1, with traverse.

III. Restriction Of The Claims Into 15 Groups Was Improper

A. The Applicants traverse the restriction of claim Groups I and VIII

Claims 57-59 of Group VIII are directed to compositions comprising the nucleic acids of Group I and constitute product claims. The nucleic acid molecules of claims 57-59 are the same nucleic acids found in Group I as shown by the dependency of claim 57 on claims 1-3 (Group I). Also, a viral vector as recited in claim 58 is encompassed by the invention of Group I (claim 4). Furthermore, there is no provision in the MPEP supports restriction between compound X from a composition comprising compound X. This, however, is the case in this restriction requirement whereas claims to the composition comprising a vector (*e.g.*, claim 58) is restricted relative to claims to the vectors themselves (*e.g.*, claim 4). Any search designed to identify documents relevant to the patentability of the claimed polynucleotides of Group I will employ the same or similar search terms and techniques as claims 57-59. Therefore, the Applicants request that the restriction requirement with respect to the claims of Groups I and Group VIII be withdrawn and the claims of these groups be examined simultaneously.

B. The Applicants traverse the restriction of claim Groups II and VII

Claims 51-56 of Group VII are directed to compositions comprising the polypeptides of Group II and constitute product claims. The Examiner has inadvertently misgrouped these product claims with the process claims 62 and 78. Claims 51-56 should be grouped with other product claims. Furthermore, there is no provision in the MPEP supports the restriction between compound X and a composition comprising compound X. This, however, is the case in this restriction requirement. Any search designed to identify documents relevant to the patentability of the claimed polypeptides of Group II will employ the same or similar search terms and techniques as claims 51-56. Therefore, the Applicants request that the restriction requirement with respect to the claims drawn to compositions comprising the same polypeptides of Groups II and the claims of Group VII, be withdrawn and these groups be examined simultaneously.

C. The Applicants traverse the restriction of claim Groups I and II

The polypeptides of Group II are encoded by the polynucleotide sequences of Group I. It is probable that a search based on the polynucleotide sequences of Group I will involve the same prior art and identify similar art compared to a search based on the polypeptides of Group II. Moreover, existing search engines permit a searcher to search translations of known polynucleotide sequences in all reading frames automatically, permitting rapid comparisons of polynucleotide and polypeptide databases. Thus, it would not be a serious burden on the Examiner to do one search based on the claims in Groups I and II. Applicants respectfully request that the restriction requirement with respect to Groups I and II, be withdrawn and these groups be examined simultaneously.

D. The Applicants traverse the restriction of Group I or Group II and Group IX

The Group IX method of diagnosing a pathological condition comprises a step of detecting or quantifying the IL-17 like polynucleotides of claims 1, 2 or 3 (Group I) or IL-17 like polypeptides of claims 13, 14, 15 (Group II). This interrelatedness is substantiated by the fact that the method claim 63 (Group IX) depends from a claim in Group I or II. If the polynucleotides of Group I or the polypeptide of Group II (product claims) are found novel and non-obvious under 35 U.S.C. §103(a), the Applicants may be entitled to rejoinder of claims to methods of using that product. See 1184 OG 86, (1996). To facilitate efficient

examination, the Applicants request that the claims of Groups I or II and Group IX be examined simultaneously. The single claim of Group IX and its relatedness to Groups I and II suggest there will be no serious burden involved. Applicants respectfully request that the restriction requirement, in respect to Groups I or II and IX, be withdrawn and these groups be examined simultaneously.

E. The Applicants traverse the restriction of Groups I and XII

The Group XII method of modulating the levels of the IL-17 like polypeptides comprises administering the nucleic acids of Group I. If the polypeptides of Group I (product claims) are found novel and non-obvious under 35 U.S.C. §103(a), the Applicants may be entitled to rejoinder of claims to methods of using that product. *See* 1184 OG 86, (1996). The Applicants hereby request that, if the product claims of Group I are allowed, the Patent Office rejoin the method claims of Group XII. To facilitate efficient examination, the Applicants request that the claims of Group I and Group XII be examined simultaneously. The single claim of Group XII and its dependency to Group I suggests that there will be no serious burden involved. Applicants respectfully request that the restriction requirement with respect to Groups I and XII, be withdrawn and these groups be examined simultaneously.

F. The Applicants traverse the restriction of Groups II and III

The process of Group III determines whether a compound inhibits the activity of a polypeptide of Group II. If the polypeptide of Group II (product claims) are found novel and non-obvious under 35 U.S.C. §103(a), the Applicants may be entitled to rejoinder of claims to processes using that product. *See* 1184 OG 86, (1996). The Applicants hereby request that, if the product claims of Group II are allowed, the Patent Office rejoin the process claim of Groups III. To facilitate efficient examination, the Applicants request that the claims of Groups II and III be examined simultaneously. The relatedness of the claims of Group III to the claims of Group II suggest that there will be no serious burden involved. Applicants respectfully request that the restriction requirement with respect to Groups II and III, be withdrawn and these groups be examined simultaneously.

G. The Applicants traverse the restriction of Groups II and XI

The Group XI method of identifying binding partners for IL-17 like polypeptides comprises contacting a compound with a composition comprising the polypeptides of Group II. If the polypeptides of Group II (product claims) are found novel and non-obvious under 35 U.S.C. §103(a), the Applicants may be entitled to rejoinder of claims to methods of using that product. *See* 1184 OG 86, (1996). The Applicants hereby request that, if the product claims of Group II are allowed, the Patent Office rejoin the method claims of Group XI. To facilitate efficient examination, the Applicants request that the claims of Group II and Group XI be examined simultaneously. The single claim of Group XI and its dependency on Group II, suggests that there will be no serious burden involved. Applicants respectfully request that the restriction requirement with respect to Groups II and XI, be withdrawn and these groups be examined simultaneously.

H. The Applicants traverse the restriction of Group II and Group IV

The antibodies of Group IV specifically bind to the polypeptides of Group II. If the search based on the polypeptides of Group II indicates these polypeptides are novel and non-obvious, the antibodies of Group IV should also be novel and non-obvious. Thus, it would not be a serious burden on the Examiner to do one search based on the claims in Group II and IV. Applicants respectfully request that the restriction requirement with respect to Groups II and IV, be withdrawn and these groups be examined simultaneously.

I. The Applicants traverse the restriction of Group IV and V

The Group V method of detecting or quantifying IL-17 like polypeptides utilize an antibody of Group IV. This interrelatedness is substantiated by the fact that method claim 31 (Group V) depends from a claim in Group IV. If the antibodies of Group IV (product claims) are found novel and non-obvious under 35 U.S.C. §103(a), the Applicants may be entitled to rejoinder of claims to methods of using that product. *See* 1184 OG 86, (1996). The Applicants hereby request that, if the product claims of Group IV are allowed, the Patent Office rejoin the method claims of Group V. To facilitate efficient examination, the Applicants request that the claims of Group IV and Group V be examined simultaneously. The small number of claims in Group V and their relatedness to Group IV suggest there will be no serious burden involved. Applicants respectfully request that the

restriction requirement with respect to Groups IV and V, be withdrawn and these groups be examined simultaneously.

J. The Applicants traverse the restriction of claim Groups IV and VI

The Group VI method claims, directed to a method of treating, preventing or ameliorating an IL-17 like polypeptide-related disease, comprises a step of administering a selective binding agent of Group IV to a patient in need. This interrelatedness of Groups IV and VI is substantiated by the fact that the claims of Group VI each depend from a claim of Group IV. If the selective binding agents of Group IV (product claims) are found novel and non-obvious under 35 U.S.C. §103(a), the Applicants may be entitled to rejoinder of the claims of Group VI to the method of using that product. *See* 1184 OG 86, (1996). The Applicants hereby request that, if the product claims of Group IV are allowed, the Patent Office rejoin the method claims of Group VI. To facilitate efficient examination, the Applicants request that the claims of Group IV and Group VI be examined simultaneously. The interrelatedness of the claims of Group IV and VI suggests that there will be no serious burden involved. Applicants respectfully request that the restriction requirement with respect to Groups IV and VI, be withdrawn and these groups be examined simultaneously.

CONCLUSION

It is respectfully requested that the restriction requirement be withdrawn, and that each of claims 1-8, 10, and 11 presently pending in this application, be examined.

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Respectfully submitted,

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